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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,082	07/06/2001	Geert Maertens	2752-50	7439

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EXAMINER
WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,082	MAERTENS ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *29,31-33,38,41,46,48 and 49* is/are allowed.

6)☐ Claim(s) *24-27,34-37,39,40,42,43 and 50* is/are rejected.

7)☒ Claim(s) *28,30,44,45,47 and 51-54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *08/256,568* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL REJECTION

1. The applicant's Response (filed 08 JAN 03) to the Office Action has been entered. Following the entry of the claim amendment(s), **Claim(s) 24-54** is/are pending. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

DRAWINGS / SPECIFICATION / SEQUENCE RULES

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because not all of the sequences shown in the figures (e.g. Figures 2A, 2B, 4A-2, 4A-3, 4B-1, 4B-2, 5A and 5B) are accompanied by a SEQ ID NO. Are all of the sequences shown in Figures present in the CRF and in the paper copy of the sequence previously provided to the USPTO. If not a new CRF and paper copy must be prepared before allowance. I apologize for missing this previously.

35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

> A person shall be entitled to a patent unless –
>
> **(a)** the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> **(e)** The invention was described in –
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligations under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

CLAIM REJECTIONS UNDER 35 USC § 102/103

6. **Claim(s) 26-27, 36-37 and 40** is/are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sommer et al. (1989).

For the following prior art rejection, Claims 26, 27, 37 and 40 have been interpreted as follows: **Claim 26** is drawn to a polynucleic acid consisting of 10 to 50 nucleotides which specifically hybridizes with SEQ ID NO: 20. **Claim 27** is drawn to a polynucleic acid consisting of 27 to 50 nucleotides which specifically hybridizes with SEQ ID NO: 27 or the complement thereof or the corresponding sequence wherein T has been replaced by U. **Claim 37** is drawn to a polynucleic acid consisting of 15 to 50 nucleotides which specifically hybridizes with at least one of SEQ ID NOs: 1, 2 or 3. **Claim 40** is drawn to a polynucleic acid consisting of 21 to 50 nucleotides which specifically hybridizes with SEQ ID NO: 20.

Sommer et al. teach the minimal homology requirements for PCR priming (i.e. specific

hybridization). Sommer et al. teach that a 17-mer requires at least three homologous nucleotides at it's 3' end for successful priming. In addition, note that Sommer et al. teach that they get weak amplification (i.e. specific hybridization) with long primers (i.e. 36-mers) having only 2 nucleotides homology.

Note that the 16th oligo recited in Table 1 is a 17-mer with a sequence which reads 5'---GCC-3'. Using the logic set forth in Sommer, all that is required for specific priming (i.e. specific hybridization) is a sequence of 5'-GGC-3 somewhere in the target oligo. Note that SEQ ID NO: 20 comprises the sequence 5'- GCC-3 at nucleotide positions 9-11. Therefore, it can be said that Sommer et al. teach a polynucleic acid which will specifically hybridize with SEQ ID NO: 20.

In addition, note that Sommer et al. teach a polynucleic acid consisting of 27 to 50 nucleotides (i.e. oligo m, a 36 –mer) which will specifically hybridizes with SEQ ID NO: 27 or SEQ ID NO: 20. Note that oligo m recited in Table 1 is a 36-mer with a sequence which reads 5'---GC-3'. Using the logic set forth in Sommer, all that is required for specific priming (i.e. specific hybridization) is a sequence of 5' -GC- 3' somewhere in the target oligo. Note that SEQ ID NO: 27 comprises the sequence 5'- GC- 3' at nucleotide positions 4-5 and that SEQ ID NO: 20 comprises the sequence 5'- GC- 3' at nucleotide positions 5-6. Therefore, it can be said that Sommer et al. teach a polynucleic acid which will specifically hybridizes with SEQ ID NOs: 27 and 20.

Also note that the 16th oligo recited in Table 1 is a 17-mer with a sequence which reads 5'---GCC-3'. Using the logic set forth in Sommer, all that is required for specific priming (i.e. specific hybridization) is a sequence of 5'-GGC-3 somewhere in the target oligo. Note that SEQ ID NO: 3 comprises the sequence 5'- GGC-3 at nucleotide positions 10-12. Therefore, it can be said that Sommer et al. teach a polynucleic acid which will specifically hybridize with SEQ ID NO: 3.

Also note that the third oligo recited in Table 1 is a 17-mer with a sequence which reads 5'---GGT- 3'. Using the logic set forth in Sommer, all that is required for specific priming (i.e. specific hybridization) is a sequence of 5'-ACC- 3' somewhere in the target oligo. Note that SEQ ID NO: 2 comprises the sequence 5'- ACC- 3' at nucleotide positions 18-20. Therefore, it can be said that Sommer et al. teach a polynucleic acid which will specifically hybridize with SEQ ID NO: 2.

Finally, note that the 9th oligo recited in Table 1 is a 17-mer with a sequence which reads 5'---AGT- 3'. Using the logic set forth in Sommer, all that is required for specific priming (i.e. specific hybridization) is a sequence of 5'-ACT- 3' somewhere in the target oligo. Note that SEQ ID NOs: 1 comprises the sequence 5'- ACT- 3' at nucleotide positions 12-14. Therefore, it can be said that Sommer et al. teach a polynucleic acid which will specifically hybridize with SEQ ID NO: 1.

Admittedly, none of the oligos taught by Sommer are perfectly homologous to, identical to, or complementary to SEQ ID NOs: 1-3, 20 or 27, however these limitation are not a requirement of the claimed invention.

Claim 36 is drawn to a process for the general amplification of the 5' UR region of HCV isolates which involves at least one primer which primer is a primer of 15 to 50 nuucleotides which specifically hybridizes with SEQ ID NO:1 or SEQ ID NO:3.

Sommer et al. teach the minimal homology requirements for PCR priming (i.e. specific hybridization). Sommer et al. teach that a 17-mer requires at least three homologous nucleotides at it's 3' end for successful priming. Also note that the 16th oligo recited in Table 1 is a 17-mer with a sequence which reads 5'---GCC-3'. Using the logic set forth in Sommer, all that is required for specific priming (i.e. specific hybridization) is a sequence of 5'-GGC-3' somewhere in the target oligo. Note that SEQ ID NO: 3 comprises the sequence 5'- GGC-3' at nucleotide positions 10-12. Therefore, it can be said that Sommer et al. teach a polynucleic acid which will specifically hybridize with SEQ ID NO: 3.

Finally, note that the 9th oligo recited in Table 1 is a 17-mer with a sequence which reads 5'---AGT- 3'. Using the logic set forth in Sommer, all that is required for specific priming (i.e. specific hybridization) is a sequence of 5'-ACT- 3' somewhere in the target oligo. Note that SEQ ID NOs: 1 comprises the sequence 5'- ACT- 3' at nucleotide positions 12-14. Therefore, it can be said that Sommer et al. teach a polynucleic acid which will specifically hybridize with SEQ ID NO: 1.

Admittedly, none of the oligos taught by Sommer are perfectly homologous to, identical to, or complementary to SEQ ID NOs: 1 or 3, however these limitation are not a requirement of the claimed invention. Also it is admitted that Sommer et al. do not teach amplifying the 5' UR region of HCV isolates. However, given the teachings of Sommer et al. this limitation is considered to be inherent to Sommer et al. Sommer et al. is teaching that any target sequence with 5'-GGC-3' within its bounds will hybridize specifically to and be primed by the 16th oligo recited in Table 1. In addition, Sommer et al. is teaching that any target sequence with 5'-ACT-3' within its bounds will hybridize specifically to and be primed by the 9th oligo recited in Table 1.

CLAIM REJECTIONS UNDER 35 USC § 103

7. **Claim(s) 34** is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Sommer et al.(1989) as applied to Claim 26-27,37 and 40 above and further in view of the Stratagene Catalog. (1988).

Claim 34 is drawn to a kit comprising at least one of the polynucleic acids of any one of a defined set of Claims which includes Claim 26-27, 37 and 40.

Sommer et al. teach all of the limitations of Claim 34 [i.e. as argued above against Claim(s) 26-27, 37 and 40] except Sommer et al. do not teach a kit comprising the oligos recited. However, as

evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Sommer et al. with the teachings of the Stratagene Catalog wherein the reagents necessary to perform the method taught by Sommer et al. are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

NONSTATUTORY DOUBLE PATENTING

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. **Claim(s) 24-26, 37, 39 42** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-2 of US Patent No. 6,495,670. Although the conflicting claims are not identical, they are not patentably distinct from each other.

10. **Claim(s) 24-25, and 27** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 of US Patent No. 6,051,696. Although the conflicting claims are not identical, they are not patentably distinct from each other.

11. **Claim(s) 34 and 50** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-2 of US Patent No. 6,495,670 or over Claim 1 of US Patent No. 6,051,696 as applied above and further in view of the Stratagene Catalog (1988).

Claims 1-2 of US Patent No. 6,495,670 teach all of the limitations of Claim 34 except this claim does not teach placing the reagents into a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Claims 1-2 of US Patent No. 6,495,670 with the teachings of the Stratagene Catalog wherein the reagents of Claims 1-2 of US Patent No. 6,495,670 are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

Claims 1 of US Patent No. 6,051,696 teach all of the limitations of Claim 50 except this claim does not teach placing the reagents into a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Claims 1-2 of US Patent No. 6,051,696 with the teachings of the Stratagene Catalog wherein the reagents of Claims 1-2 of US Patent No. 6,051,696 are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits.

12. **Claim(s) 24-27 and 35** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of US 6,051,696. Although the conflicting claims are not identical, they are not patentably distinct from each other.

13. **Claim(s) 43** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 11 of US 5,846,704. Although the conflicting claims are not identical, they are not patentably distinct from each other.

14. **Claim(s) 34** is/are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1 of US 6,051,696 as applied above and further in view of the Stratagene Catalog (1988).

Claim 1 of US 6,051,696 teach all of the limitations of Claim 34 except this claim does not teach placing the reagents into a kit. However, as evidenced by the Stratagene Catalog teaching, it was well known at the time of the invention to place the reagents needed to perform a nucleic acid based assay into a kit format. Therefore, absent an unexpected result, it would have been *prima facie* obvious to the ordinary artisan at the time of the invention to modify the teachings of Claim 1 of US 6,051,696 with the teachings of the Stratagene Catalog wherein the reagents of Claim 1 of US 6,051,696 are placed into a kit format. The ordinary artisan would have been motivated to make this modification in order to take advantage of the savings and efficiency afforded by kits. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

CLAIM OBJECTIONS

15. **Claim(s) 28, 30, 44-45, 47 and 51-54** is/are objected to because it is dependent upon a rejected independent base claim.

ALLOWABLE SUBJECT MATTER

16. **Claim(s) 29, 31-33, 38, 41, 46, 48 and 49** is/are allowable over the prior art of record.

CONCLUSION

17. **Claim(s) 29, 31-33, 38, 41, 46, 48 and 49** is/are allowable while **Claim(s) 24-28, 30, 34-37, 39-40, 42-45, 47, 50-54** is/are rejected and/or objected to for the reason(s) set forth above.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

ETHAN WHISENANT
PRIMARY EXAMINER